K072131

As required by 21 CFR 807.92 (c) this 510(k) summary is prepared

Application Date:

11th May 2007

AUG 17 2007

Applicant:

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Proposed Device:

Blood Gas Monitor
Trade Name: M3 Monitor
Classification Name: Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass
21 CFR 870.4330, Product code: DRY

Predicate Devices:

Oxygen Saturation and Hematocrit / Haemoglobin Concentration:-

K071725 Spectrum Medical Ltd, M2 Monitor.

Flow:-

K872048 Transonic Inc. – Transonic Flowmeter (for flow measurement components).

Description of Proposed Device:

The Spectrum M3 Monitor consists of a 10.4 inch high definition touch screen and four active measuring channels mounted into a flat panel unit. Sensor cables are used to connect the active measuring channels to the external surface of extracorporeal blood line tubing. Two active measuring channels are used to measure venous and arterial oxygen saturation. The sensor cable head contains a light emitting diode that sends light through the extracorporeal tube, which illuminates the blood. The reflected spectra is collected by a fibre optic cable and quantified by a photo detector contained within a spectrometer. These spectra are

compared to reference spectra by the monitor's software to determine the oxygen saturation of the blood. The third active measuring channel is used to measure hematocrit or haemoglobin concentration. The sensor cable head contains a light emitting diode that transmits near-infra-red light through the extracorporeal tube. A photo diode measures a received light level. The level of signal attenuation is used to calculate hematocrit or haemoglobin concentration.

The fourth active measuring channel is used to measure blood flow using Transonic proprietary technology. Flow measurement is accomplished by measuring the difference in transit time between a pair of upstream and down stream ultrasonic transducers.

Parameter values are displayed in both a digital and trended format. The M3 Monitor has been designed to self-detect the selected sensor and to automatically configure the required parameter display screens. The device can be configured by the trained clinician to set parameter specific alarms and to select either the display of hematocrit or haemoglobin concentration. Session data can be stored to a memory card supplied with the system or via a RS232 link to a remote computer.

The M3 Monitor is powered from the AC Mains supply and also incorporates a battery back-up that automatically switches on in the event of an interruption to the mains power supply. The system weighs 4.5 kg and is supplied with a pole mount clamp.

Intended Use of Proposed Device

The intended use of the M3 Monitor is for the non-invasive continuous monitoring of oxygen saturation, hematocrit / haemoglobin concentration and flow of the blood in an extracorporeal circuit. The device provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarm levels.

Summary of Technological Characteristics

Oxygen Saturation and Hematocrit / Haemoglobin Concentration:-

The proposed device has the same technological characteristics as the predicate M2 monitor cleared under 510(k) K0712725.

Flow:-

There are no differences between the proposed and Transonic Flowmeter device with respect to flow measurement. Both devices are manufactured, quality control tested, and calibrated under the same controls and procedures. Known flow rates using a "gold-standard" flow sensors, which are tested by timed fluid collection using NIST traceable stopwatch and volume standards, are utilized for 100% flow board and sensor calibration.

Substantial Equivalence Determination

The M3 Monitor has an intended use that is also featured in its two predicate devices. Performance data has been provided to show that the M3 Monitor can

measure the oxygen saturation, hematocrit / haemoglobin concentration and flow of blood in extracorporeal blood tubing to an equivalent accuracy of the predicate devices. The M3 Monitor is therefore considered substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2007

Spectrum Medical Ltd.
c/o Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories Inc.
12 Laboratory Drive
Research Triangle, NC 27709

Re: K072131
M3 Monitor
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary bypass on-line blood gas monitor
Regulatory Class: Class II (two)
Product Code: DRY
Dated: July 30, 2007
Received: August 2, 2007

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072131

Device Name: M3 Monitor

Indications for Use:

The M3 Monitor is intended as a device for the non-invasive continuous monitoring of oxygen saturation, hematocrit and haemoglobin concentration and the flow of the blood in an extracorporeal circuit.

The device provides monitoring information to trained clinicians and can be configured by them to alarm to set parameter specific alarms.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072131